

REMARKS/ARGUMENTS

Claims 1-23 and 25-39 are active in this application.

Claim 1 is amended to indicate that the aqueous phase comprises a physiologically acceptable medium suitable for topical application.

Claim 20 is amended to indicate suitability for cosmetic application.

Support for the amendment is found on page 27, lines 9-18.

No new matter is added.

Applicants thank Examiner Foelak for the courteous discussion granted to the Applicants' undersigned representative on August 10, 2004.

During this discussion, the undersigned explained that Yeo does not describe or suggest a composition with comprises an aqueous phase and a polymer with water-soluble units and units having in water a lower critical solution temperature LCST, the heat induced demixing temperature in aqueous solution of the units with an LCST being from 5 to 40°C for a concentration of said units in water of 1% by mass, and the concentration of said polymer in said composition being such that its gel point is in the range from 5 to 40°C. The substance of this discussion is expanded upon in the remarks made below.

The rejection of Claims 1-23 and 25-39 under 35 U.S.C. §103(a) over Yeo (US 5,509,913) is respectfully traversed.

Yeo describes flushable compositions and flushable products, such as flushable personal hygiene articles, flushable medical, hospital and surgical supplies, and flushable household wipes and packaging material that have sufficient wet tensile strength for their intended use in the presence of body waste fluids, but which disintegrate and disperse in the presence of ordinary tap water so as to be flushable in a conventional toilet and disposable in municipal or private sewage system without obstructing or clogging the toilet or sewage system (see Abstract). To achieve the invention, Yeo describes that "polymers that exhibit a

lower critical solution temperature (LCST) or cloud point close to 25 °C in water are potential suitable materials” (see col. 9, lines 26-28). However, Yeo fails to describe the exact volume fraction at which the LCST occurs and certainly fails to provide any description or suggestion for polymer with water-soluble units and units having in water a lower critical solution temperature LCST as claimed.

As shown in the attached publication of Young and Lovell (“Introduction to Polymers,” 2nd Edition, pages 203-210), LCST is determined by finding the point where the bimodal and the spinodal points meet. The point is specified at a specific critical temperature and at a specific volume (weight) fraction of the polymer in solvent (water in this case). The LCST behavior is important for the present invention as well as in Yeo’s invention as above the curve delineated by the LCST phase diagram, the polymer becomes immiscible with the solvent, whereas below the curve, the polymer is miscible with water.

In this respect, based on the description, Yeo would not select the LCST volume fraction to occur at 1wt% as presently claimed, but rather at a higher weight fraction of the polymer. To illustrate this point, the Examiner’s attention is referred to two hypothetical LCST phase diagrams where one graph depicts the preferred phase diagram of Yeo and the other graph is an example of the present invention.

When a diaper, which is what Yeo describes, is soiled by bodily fluid, the content of water is low relative to the polymer. In this situation, Yeo would specifically desire the polymer to be immiscible with the water thereby preventing the diaper from falling apart. However, once disposed in the toilet, the water content significantly increases and thus the diaper would become soluble in the toilet. This situation is exemplified by the hypothetical graph depicted as “Yeo graph.”

However, if the critical weight content of the polymer at which LCST occurs is at 1wt% (see “present invention” curve), Yeo would not be able to achieve the desired outcome

as the phase miscibility boundary shifts toward higher temperatures with increasing polymer content. Thus, soiled diapers would dissolve with the small amount of bodily fluids even before flushing the diaper and certainly would defeat the core purpose of the invention described by Yeo. As a result, Yeo would not want to prepare a flushable composition that employed a polymer as in the present claims because doing so would result in something that would fail to meet the requirements of a flushable product, such as a diaper. Further guidance on this issue is found in M.P.E.P. Section 2141.02: "PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS."

In the present invention, however, Applicants describe that "the phenomenon of gelation may also be reinforced in the presence of warm water, generally at a temperature of 30 to 40 °C" (see page 4, lines 23-25). In another words, the gelation phenomenon is enhanced with increasing content of water (decreasing content of polymer).

The LCST occurring at 1wt% which is part of the present invention is not described or suggested by Yeo.

Furthermore, as Yeo is concerned with flushable compositions and flushable products, Yeo provides no suggestion to select those polymers comprising units with LCST having a heat-induced demixing temperature of 5 to 40°C which are particularly advantageous when the composition is used topically, e.g., on the surface of the skin. The generation of foam from the claimed composition is particularly useful as a topical composition within this demixing temperature range but the Examiner should recognize that demixing temperatures above 40°C or below 5°C would not typically be useful in such topical applications, e.g., using the composition on the skin.

As a consequence, the claimed composition is not described in Yeo nor would one have selected the polymers provided in the claims from the description in Yeo.

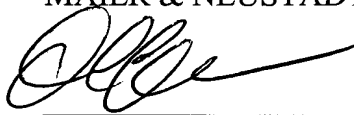
Application No. 10/070,922
Reply to Office Action of May 19, 2004

Withdrawal of the rejection is requested.

Applicants submit the application is now in condition for allowance. Early notification of such allowance is earnestly requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Richard L. Treanor, Ph.D.
Attorney of Record
Registration No. 36,379

Daniel J. Pereira, Ph.D.
Registration No. 45,518

Customer Number
22850

Introduction to Polymers

Second Edition

R.J. Young

*Professor of Polymer Science and Technology
Manchester Materials Science Centre
University of Manchester and UMIST*

and

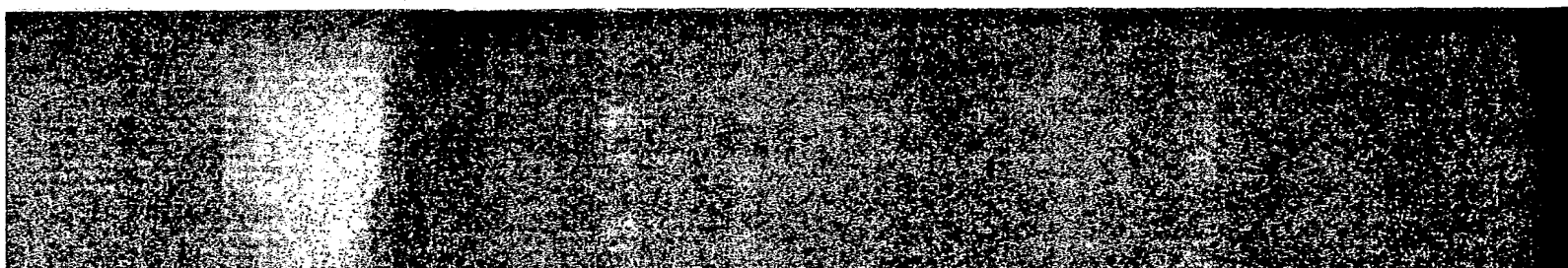
P.A. Lovell

*Lecturer in Polymer Science and Technology
Manchester Materials Science Centre
University of Manchester and UMIST*



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ome indication of molar mass can be obtained by sedimentation equilibrium measurements. These methods are often used in solution and will be given only brief

a polymer molecule in solution and does not cause distortion of the sedimentation boundary. In ultracentrifugation, which can attain rotation rates of up to 70 000 rpm and generate accelerations of up to $10^5 g$, the acceleration due to rotation fits into the rotor of the cell. The cell is in the form of a sector and the sedimentation boundary would be located at a distance from the axis of rotation. The sedimentation process gives rise to a concentration gradient which is counteracted by outward diffusion of the components. In sedimentation equilibrium, the broadening of the sedimentation boundary also increases with increasing molar mass. The radial variation of concentration in ultracentrifugation can be determined by light scattering and other methods by which they will now be briefly

the cell is rotated at a constant speed until an equilibrium is reached. The tendency of the components to migrate down the concentration gradient developed is counteracted by the centrifugal force so that the concentration profiles for the components are determined. The sedimentation equilibrium method is used to determine \bar{M}_z to be determined by sedimentation equilibrium measurements, since this is at least

the solution cell at

very high speeds (typically 60 000–70 000 rpm) and gives results in much shorter timescales than sedimentation equilibrium measurements. The movement of the boundary layer is monitored as a function of time and its steady-state velocity used to calculate the mean sedimentation coefficient, S_0 , for the polymer in solution. Measurements are made for a series of solution concentrations and enable the limiting sedimentation coefficient, S_0 , to be obtained by extrapolation to $c = 0$. In order to calculate an average molar mass, it is necessary either to know the limiting diffusion coefficient of the polymer in the solvent or to calibrate the system by measuring S_0 for a series of similar polymers but which have narrow molar mass distributions and known molar masses. The latter procedure is more common and an equation similar in form to the Mark-Houwink Equation (3.160) is used to correlate S_0 data with molar mass for each specific polymer/solvent/temperature system. The resulting average molar mass is usually close to \bar{M}_w .

Molar Mass Distribution

3.16 Fractionation

In many instances, average molar masses and their ratios (i.e. polydispersity indices) are insufficient to describe the properties of a polymer and more complete information on the molar mass distribution is required. One way of obtaining this information is to separate (i.e. *fractionate*) the polymer into a number of fractions each of which has a narrow distribution of molar mass. The weight and molar mass of each polymer fraction are determined and enable the molar mass distribution to be constructed in the form of a histogram. However, such procedures are rarely used nowadays because much more rapid and powerful methods of size-exclusion chromatography (Section 3.17) are available for determining molar mass distributions. Nevertheless, fractionation itself is still practised, often for purposes of purification, and will be considered here in some detail because it introduces the important topic of phase-separation behaviour of polymers.

3.16.1 Phase-separation behaviour of polymer solutions

The simplest procedure for polymer fractionation is to dissolve the polymer at low concentration in a poor solvent and then to bring about stepwise phase separation (i.e. 'precipitation') of polymer fractions by either changing the temperature or adding a non-solvent. The highest molar mass species phase separate first and so the fractions are obtained

in order of decreasing molar mass. Phase separation can be treated theoretically on the basis of Flory-Huggins theory. The effect of temperature upon phase separation of solutions of non-crystallizing polymers will be considered here since it is easier to analyse. It is usual to deal with molar quantities and so both sides of the Flory-Huggins Equation (3.22) must be divided by $(n_1 + n_2x)$ where n_1 and n_2 are the numbers of moles of solvent and polymer present, and x is the number of segments in each of the polymer molecules (Section 3.2.2) which are assumed to be *monodisperse*. This gives the following equation for ΔG_m^* , the Gibbs free energy of mixing per mole of lattice sites (which therefore can be considered to be the Gibbs free energy of mixing per mol of segments)

$$\Delta G_m^* = RT[\phi_1 \ln \phi_1 + (\phi_2/x) \ln \phi_2 + \chi \phi_1 \phi_2] \quad (3.16)$$

This equation describes a series of curves for the variation of ΔG_m^* with ϕ_2 , the volume fraction of polymer, one for each temperature. The curves

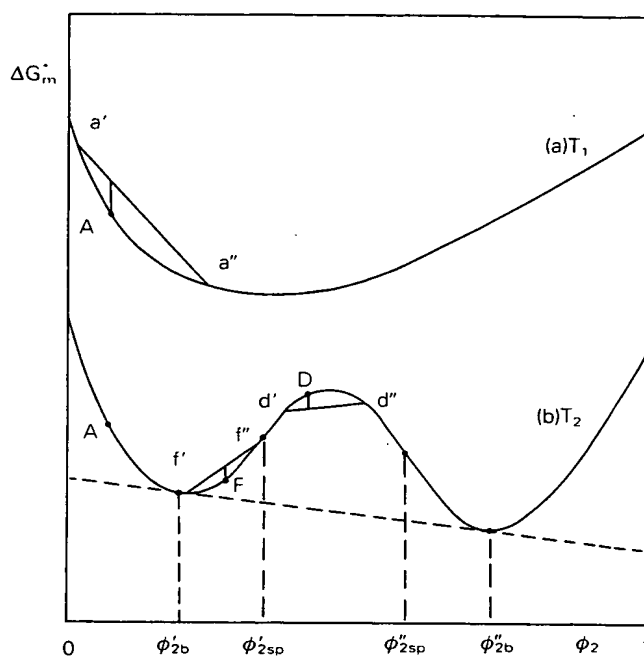


Fig. 3.19 Schematic illustration of the variation of ΔG_m^* with ϕ_2 at two temperatures (a) T_1 and (b) T_2 .

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have one of two general forms, as depicted in Fig. 3.19 which shows schematically curves that would be consistent with low values of x . At temperature T_1 (Fig. 3.19(a)) the polymer and solvent are miscible in all proportions, as is evident from consideration of any point on the curve. For example, if a homogeneous solution with $\phi_2 (= \phi_{2A})$ corresponding to point A were to separate into two co-existing phases, conservation of matter demands that one should have $\phi_2 < \phi_{2A}$ and the other $\phi_2 > \phi_{2A}$, e.g. corresponding to points a' and a'' . It is a relatively simple matter to show that the Gibbs free energy change associated with the phase separation process is given by the difference between (i) the value of ΔG_m^* corresponding to the point of intersection of the tie-line (joining points a' and a'') with the vertical $\phi_2 = \phi_{2A}$ line, and (ii) the value of ΔG_m^* on the curve at A. Clearly this difference is positive for all points on the curve and so the existence of a single homogeneous phase is favoured for all ϕ_2 .

The situation at temperature T_2 (Fig. 3.19(b)) is rather more complex since two ΔG_m^* minima are present. Consider again phase separation from a homogeneous solution corresponding to ϕ_{2A} . It is easy to see that tie-lines joining any two points on the curve either side of ϕ_{2A} will intersect the vertical $\phi_2 = \phi_{2A}$ line above the curve. This is true for all compositions in the ranges $0 < \phi_2 < \phi'_{2b}$ and $\phi'_{2b} < \phi_2 < 1$ and so homogeneous solutions with ϕ_2 in these ranges are stable at T_2 . Now consider phase separation of a homogeneous solution with $\phi_2 (= \phi_{2D})$ corresponding to point D. The tie-lines joining two points (such as d' and d'') immediately on either side of ϕ_{2D} intersect the vertical $\phi_2 = \phi_{2D}$ line below the curve. Thus the homogeneous solution is unstable and phase separation takes place until the system becomes stable when the two co-existing phases have the binodal compositions ϕ'_{2b} and ϕ''_{2b} . All homogeneous solutions with compositions in the range $\phi'_{2sp} < \phi_2 < \phi''_{2sp}$ are similarly unstable and separate into two phases corresponding to ϕ'_{2b} and ϕ''_{2b} . The general condition for equilibrium between two co-existing phases is that for each component, the chemical potential must be the same in both phases, i.e. $\mu'_1 = \mu''_1$ and $\mu'_2 = \mu''_2$. This condition is usually written in terms of chemical potential differences

$$\mu'_1 - \mu_1^0 = \mu''_1 - \mu_1^0 \quad (3.168a)$$

$$\mu'_2 - \mu_2^0 = \mu''_2 - \mu_2^0 \quad (3.168b)$$

since these are more directly related to ΔG_m^* . It can be shown that for any point on the curve, $(\mu_1 - \mu_1^0)$ and $(\mu_2 - \mu_2^0)/x$ are given by the values of ΔG_m^* which correspond to the intersections of the tangent to the curve at that point, with the vertical $\phi_2 = 0$ and $\phi_2 = 1$ lines respectively. Thus Equations (3.168a/b) are satisfied when two points on the curve have a common tangent as for ϕ'_{2b} and ϕ''_{2b} in Fig. 3.19(b). Since the variation of

ΔG_m^* with ϕ_2 is unsymmetrical for polymer solutions, the binodal points do not correspond to the minima in the curve.

Finally, consider a homogeneous solution with $\phi_2 (= \phi_{2F})$ corresponding to point *F* on the curve for T_2 . Clearly phase separation into two phases corresponding to the binodal compositions is thermodynamically favoured. However, in order for this to occur an energy barrier must be overcome because the initial stages of phase separation about ϕ_{2F} (e.g. to points *f'* and *f''*) give rise to an increase in the Gibbs free energy. This is true for all homogeneous solutions with compositions in the ranges $\phi'_{2b} < \phi_2 < \phi'_{2sp}$ and $\phi''_{2sp} < \phi_2 < \phi''_{2b}$, where ϕ'_{2sp} and ϕ''_{2sp} are the *spinodal compositions* corresponding to the points of inflection in the curve. Such solutions are said to be *metastable* and will phase separate to the binodal compositions, but only if the energy barrier can be overcome. Since the spinodal compositions occur at points of inflection, they are located by application of the condition

$$\left(\frac{\partial^2 \Delta G_m^*}{\partial \phi_2^2} \right)' = \left(\frac{\partial^2 \Delta G_m^*}{\partial \phi_2^2} \right)'' = 0 \quad (3.169)$$

The existence of two minima in the variation of ΔG_m^* with ϕ_2 (and hence phase separation) results from the contribution to ΔG_m^* due to contact interactions (i.e. non-zero ΔH_m). This contribution decreases as the temperature changes from T_2 towards T_1 , and the binodal and spinodal points get closer together until at a *critical temperature* T_c they just coincide at a single point corresponding to ϕ_{2c} . The curves defined by the binodal points and spinodal points as a function of temperature are known as the *binodal* and *spinodal* respectively. For most polymer solutions ΔH_m is positive, so that T_c ($> T_2$) corresponds to the *common maximum* of the binodal and spinodal, and is known as the *upper critical solution temperature (UCST)* above which the polymer and solvent are miscible in all proportions (see Fig. 3.20(a)). For the less common situation when ΔH_m is negative, T_c ($< T_2$) corresponds to the *common minimum* of the binodal and spinodal, and is known as the *lower critical solution temperature (LCST)* below which the polymer and solvent are completely miscible (see Fig. 3.20(b)). LCST behaviour usually is observed when there are specific favourable polymer-solvent interactions (e.g. hydrogen bonding, charge transfer). The last two examples given in Table 3.1, and poly(ethylene oxide) in water, are systems which show LCST behaviour due to hydrogen bonding interactions. LCST behaviour can also be caused by volume contraction upon mixing because this leads to a reduction in the entropy of mixing. Flory-Huggins theory assumes there to be no volume change and so more advanced theories are required to account quantitatively for the effects of volume changes. Such theories predict that all polymer-solvent systems should show both UCST and LCST behaviour,

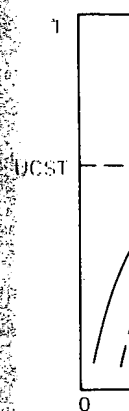


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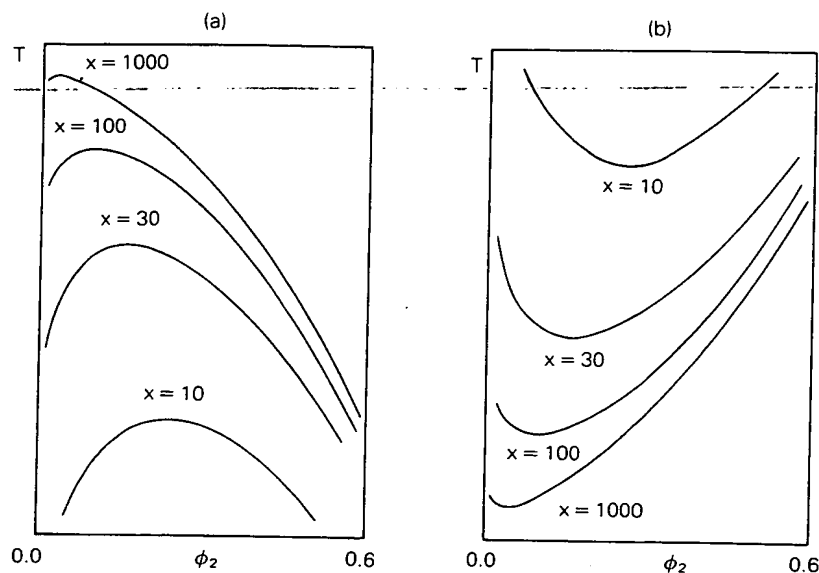


Fig. 3.21 The effect of the number of chain segments, x , upon the binodals for (a) UCST behaviour and (b) LCST behaviour.

The critical value χ_c of the Flory-Huggins interaction parameter is obtained by substituting Equation (3.172) into (3.171)

$$\chi_c = \frac{1}{2} \left[1 + 2/x^{1/2} + 1/x \right] \quad (3.173)$$

It should be noticed that as $x \rightarrow \infty$, $\phi_{2c} \rightarrow 0$ and $\chi_c \rightarrow \frac{1}{2}$. Thus there exist unique pairs of binodal and spinodal curves for each value of x . As x increases, these curves become increasingly skewed towards the $\phi_2 = 0$ axis and T_c moves either to higher temperatures for UCST behaviour or lower temperatures for LCST behaviour (Fig. 3.21). For phase separation of a solution of a polydisperse polymer, the binodal, spinodal and values of ϕ_{2c} and χ_c are obtained by replacing x by its number-average value, and are intermediate to those of the individual polymer species with specific values of x . The origin of fractionation by phase separation now is clearly evident, since preferential phase separation of the highest molar mass species can be expected.

The chemical potential difference $\mu_{2x} - \mu_{2x}^0$ for polymer species with x chain segments can be obtained from Equation (3.27) and is given by

$$\mu_{2x} - \mu_{2x}^0 = RT [\ln \phi_{2x} - (x-1)\phi_1 + x\chi\phi_1^2] \quad (3.174)$$

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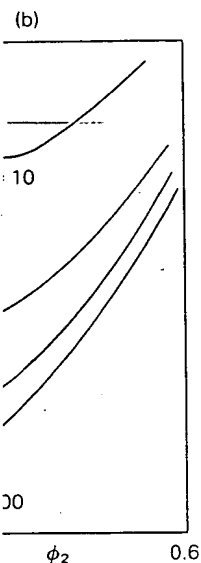
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polymer species with x and is given by

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and the equilibrium condition for their presence in two co-existing phases may be written from Equation (3.168b) as

$$\mu'_{2x} - \mu^0_{2x} = \mu''_{2x} - \mu^0_{2x} \quad (3.175)$$

The equilibrium conditions defined by Equations (3.168a) and (3.175) can be combined to give an equivalent single equilibrium condition

$$\mu'_{2x} - x\mu'_1 = \mu''_{2x} - x\mu''_1 \quad (3.176)$$

Substituting into this equation expressions for μ'_1 and μ''_1 from Equation (3.26) (in which x is replaced by \bar{x}_n and $\phi_2 = \sum \phi_{2x}$), and for μ'_{2x} and μ''_{2x} from Equation (3.174), after simplification gives

$$\phi''_{2x}/\phi'_{2x} = e^{\sigma x} \quad (3.177)$$

where the parameter σ is given by

$$\sigma = \ln(\phi''_1/\phi'_1) + 2\chi(\phi''_2 - \phi'_2) \quad (3.178)$$

For two particular co-existing phases the volume fractions in Equation (3.178) and χ have specific values, and σ is a constant. Since phase separation occurs when $\chi > \frac{1}{2}$ (because $\bar{x}_n < \infty$), σ is positive and so from Equation (3.177) $\phi''_{2x} > \phi'_{2x}$ for all values of x . Assuming that the polymer density is independent of x , then on the basis of Equation (3.177) the ratio of the mass fractions f''_{2x} and f'_{2x} of the x -mers is given by

$$f''_{2x}/f'_{2x} = R e^{\sigma x} \quad (3.179)$$

where $R = V''/V'$, and V'' and V' are the volumes of the concentrated and dilute co-existing phases respectively. Efficient fractionation requires that $\sigma \ll 1$ and $R \ll 1$. The value of σ is not easily varied, but typically is about 0.01 and so is satisfactory. In contrast, the value of R can be altered and in order to ensure that $V' > V''$ it is necessary to begin with very dilute homogeneous solutions (typically with c about 2 g dm^{-3}). The data given in Table 3.9 clearly show that whilst all species are present in each phase, the concentrated phase contains almost all of the high molar mass species. The volume fraction ratio ϕ''_{2x}/ϕ'_{2x} is close to unity for the low molar mass species so they are present predominantly in the dilute phase because of its

TABLE 3.9 Some values of ϕ''_{2x}/ϕ'_{2x} and f''_{2x}/f'_{2x} , calculated from Equations (3.177) and (3.179) with $\sigma = 0.01$ and $R = 0.005$

x	10	100	500	1000	5000
ϕ''_{2x}/ϕ'_{2x}	1.1	2.7	148.4	2.2×10^4	5.2×10^{21}
f''_{2x}/f'_{2x}	0.006	0.014	0.74	110	2.6×10^{19}

much larger volume. Thus the polymer present in the concentrated phase has a relatively narrow molar mass distribution, typically with \bar{M}_w/\bar{M}_n in the range 1.1–1.3.

Flory–Huggins theory gives reasonable predictions for phase separation of dilute polymer solutions because the excluded volume is close to zero under the conditions of phase separation. The limitations of the theory presented here arise principally from the unsatisfactory assumptions that χ is independent of ϕ_2 and that the volume change upon mixing is zero. Whilst the prediction of T_c generally is good, experimentally-determined binodals tend to be less sharp with ϕ_{2c} larger than predicted by the theory. Better agreement can be gained by taking into account the dependence of χ upon ϕ_2 and the effects of volume changes, but such theories are beyond the scope of this book.

Measurements of T_c can be used to determine theta temperatures. Comparison of the Flory–Huggins dilute solution Equations (3.38) and (3.45) leads to

$$\chi - \frac{1}{2} = \psi \left[\left(\frac{\theta}{T} \right) - 1 \right] \quad (3.180)$$

At $T = T_c$, χ can be substituted by χ_c from Equation (3.173) to give after rearrangement

$$1/T_c = 1/\theta + (1/\psi\theta)[1/x^{1/2} + 1/2x] \quad (3.181)$$

in which x is replaced by \bar{x}_n for a polydisperse polymer. Thus a plot of $1/T_c$ against $(1/\bar{x}_n^{1/2} + 1/2\bar{x}_n)$ gives a straight line with intercept $1/\theta$. It is found that theta temperatures obtained in this way are in good agreement with those obtained from osmotic pressure measurements (Section 3.6.2). Inspection of Equation (3.181) reveals that $T_c \rightarrow \theta$ as $x \rightarrow \infty$, thus providing another alternative definition of θ as the critical temperature for miscibility in the limit of infinite molar mass.

3.16.2 Procedures for fractionation

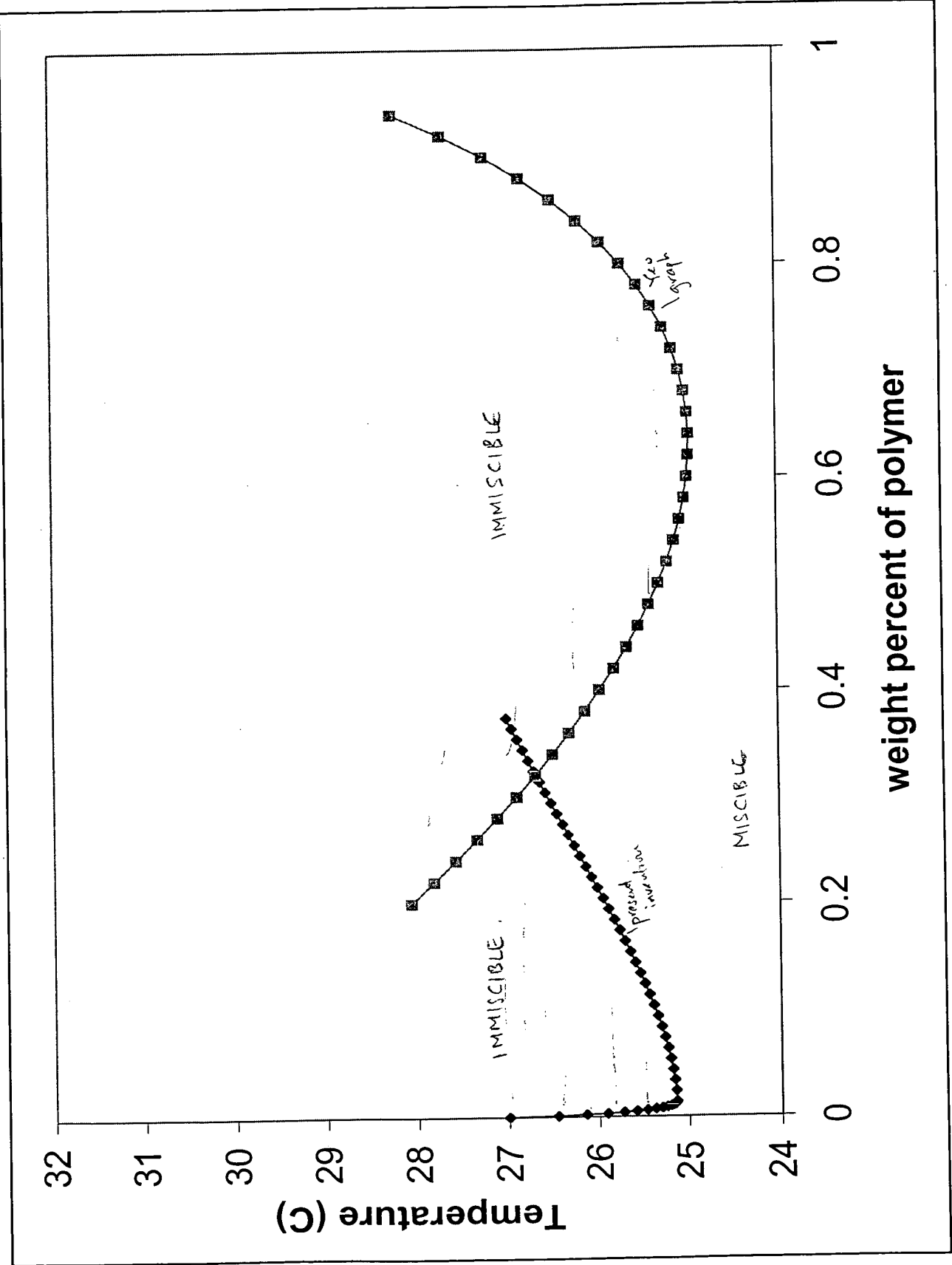
The basic requirements for fractionation were established in the preceding section. Thus phase separation of a very dilute polymer solution is brought about by causing the solvency conditions to deteriorate (i.e. causing χ to increase). This can be achieved either by adding a non-solvent to the solution or by changing the temperature. The former procedure is preferred and involves addition of non-solvent to the polymer solution until phase separation is clearly evident. The addition of non-solvent is stopped at this point and the solution heated (assuming UCST behaviour) to redissolve the concentrated phase (i.e. χ is decreased). This solution then is cooled *slowly* to achieve equilibrium phase separation. After allowing the concentrated phase to settle at the bottom of the fractionation

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